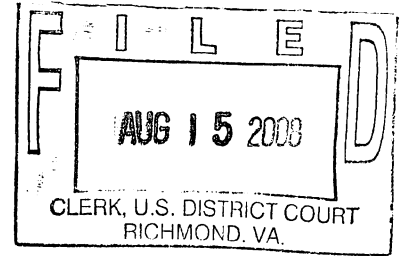


IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
RICHMOND DIVISION



PROVIDENT PHARMACEUTICAL, INC.,

Plaintiff,

v.

Civil Action Number 3:08CV393

AMNEAL PHARMACEUTICALS, LLC, et al.,

Defendants.

**MEMORANDUM OPINION**

THIS MATTER comes before the Court on Plaintiff Provident Pharmaceutical, Inc.'s Motion for Temporary Restraining Order and Preliminary Injunction. Following a hearing on July 3, 2008 and for the reasons set forth below, the Court entered an Order on July 8, 2008 DENYING Provident's motion.

**I. BACKGROUND**

In 2004, Amneal,<sup>1</sup> a Delaware company with its principal place of business in Paterson, New Jersey, and Provident, a Virginia corporation, entered into two agreements, wherein Provident agreed to fund the development of an abbreviated new drug application ("ANDA") for Metformin<sup>2</sup> and

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<sup>1</sup>In early 2004, Amneal was a start-up company interested in becoming a manufacturer and packager of generic pharmaceutical drugs. A generic drug company must have an ANDA before it can sell a given drug, which it obtains from the FDA.

<sup>2</sup>Metformin is an oral medication used to treat type-2 diabetes. Amneal manufactures, packages, and labels Metformin for Provident. Provident distributes and sells Metformin to chain stores, wholesalers, and distributors.

Benzonatate.<sup>3</sup> In return, Amneal gave Provident exclusive rights to market Metformin throughout the world and Benzonatate throughout the United States.

Pursuant to the agreements, Provident spent approximately \$750,000<sup>4</sup> to fund the ANDAs for these projects. Additionally, in the Benzonatate Agreement, the parties agreed to a Profit Sharing Formula, as developed by Amneal's business partner, Satish P. Patel ("Tish Patel"). The formula distributed the profits amongst all of the parties, including Amneal, Tish Patel, Tish Technologies ("Tishtech"), Orit Laboratories, LLC ("Orit"), Swiss Caps AG, and Provident. The contract provided that (1) Provident would receive a fee of 30%, which would be deducted prior to the profit sharing calculations; (2) net profits would be divided 30% each to Amneal and Provident, and 40% to Swiss Caps; and (3) Amneal and Tish Patel would split Amneal's portion of the net profits equally.

But, after Amneal found additional investors and capital near the end of 2006, Provident alleges, Amneal, Tish Patel, Tishtech, Orit, Tishtech, and Swiss Caps began to use numerous illegal and dishonest tactics to attempt to force Provident (1) to rewrite the Profit Sharing Formula to benefit the Defendants and (2) to agree to forego Provident's exclusive marketing and distribution rights and allow Amneal and its newly acquired affiliates and subsidiaries to market and distribute both Benzonatate and Metformin. Provident further alleges that Amneal has materially breached the Metformin Agreement by failing to ship Metformin tablets to Provident in accordance with

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<sup>3</sup>Benzonatate is an oral medication that is used to relieve coughs due to colds and influenza. Benzonatate is manufactured by Swiss Caps, located in Kirchberg, Switzerland, and sold in bulk to Amneal. Amneal packages and labels Benzonatate for Provident, which distributes and sells the Benzonatate to chain stores, wholesalers, and distributors.

<sup>4</sup>Provident spent approximately \$550,000 on the Metformin Agreement and approximately \$200,000 on the Benzonatate Agreement.

Provident's purchase orders and instructions, and by purporting to terminate the Metformin Agreement prior to the five-year minimum production period<sup>5</sup> in an attempt to force Provident to renegotiate the Benzonatate and Metformin Agreements. Accordingly, Provident requests the Court to enter an injunction (1) requiring Amneal to provide Provident with Metformin and Benzonatate pursuant to the contractual agreements between them, and (2) prohibiting Amneal from marketing or distributing Metformin anywhere and Benzonatate in the United States through itself or any of its affiliate or subsidiaries.

In response, Amneal maintains that it has fully and faithfully performed its obligations to Provident under both agreements. With respect to the Metformin Agreement, Amneal first explains that it advised Provident that the manufacture, packaging and shipment of finished Metformin product requires a minimum of twelve weeks of production lead time once the Active Pharmaceutical Ingredient ("API")<sup>6</sup> has been successfully obtained by Amneal's API supplier. Despite Amneal's request for lead time, Amneal claims that Provident has insisted on obtaining product within a shorter time frame. Amneal further asserts that it properly terminated the contract under section 9.3 of the Metformin Agreement, which provides as follows:

**Termination Without Cause After Development:** Provident or Amneal may terminate this agreement during the manufacturing and sale phase for any reason by twelve months prior written notice to the other party.

(Compl., Ex. 1.) Pursuant to section 9.3, Amneal issued Provident a written notice of termination

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<sup>5</sup>Provident relies on section 5.1 of the Metformin Agreement, which provides in pertinent part that Amneal will "continue to manufacture Product for a period of no less than five (5) years following approval of the ANDA."

<sup>6</sup>The finished dose of a pharmaceutical product is traditionally composed of (1) the API, which is the actual drug substance itself, and (2) a pharmaceutically inert substance, an excipient, which is the delivery method for the API (i.e. the gel cap in a soft gel). (Patel Aff. ¶22.)

on August 17, 2007 and, therefore, the Metformin Agreement will terminate on August 17, 2008.

Amneal also denies that it breached the sales and marketing provision of the Metformin Agreement.

Amneal also challenges Provident's claim that it breached the Benzonatate Agreement. Amneal essentially argues that Provident breached the agreement by issuing purchase orders that ignored the fact that Amneal needs four to six months of lead time to manufacture, package, and ship finished Benzonatate. The Benzonatate Agreement requires Provident to provide Amneal with sales forecasts and Amneal, in turn, is obligated to manage the inventory with Swiss Caps, including the acquisition of API consistent with that forecast. Amneal maintains that Provident failed to provide meaningful forecasting information to Amneal until after FDA approval of the Benzonatate ANDA was received.

Regarding the exclusivity provision of the Benzonatate Agreement, Amneal states that it has never initiated contact with existing or potential customers for the specific purpose of soliciting Benzonatate sales for Amneal. Instead, Amneal has sold Benzonatate to Provident exclusively and has never attempted to sell or actually sold any Benzonatate product to any other third parties. Amneal represents that (1) it is and will continue to perform in good faith under the Benzonatate Agreement; (2) it has made every effort to obtain additional Benzonatate from Swiss Caps, but Swiss Caps refuses to supply the product to Amneal; and (3) because Amneal is contractually obligated to purchase Benzonatate exclusively from Swiss Caps, it is not able to satisfy Provident's request.

Finally, both parties note that both agreements outline a dispute resolution process which culminates in binding and final arbitration. Specifically, the agreements provide that in the event of a dispute, the parties will attempt in good faith to agree on their rights concerning the dispute. If no agreement is reached within thirty days, either party may demand mediation. If mediation is

unsuccessful, either party may demand arbitration of the matter within thirty days after good faith mediation. Although Provident acknowledges that both agreements contain arbitration clauses, Provident notes that under the rules of the American Arbitration Association a party may request a court to address interim measures, such as injunctive relief and measures for the protection or conservation of property and disposition of perishable goods. (Pl.'s Mem. Supp. Mot. TRO, Ex. 2.)<sup>7</sup> Amneal, on the other hand, points out that Provident never issued a notice of breach to Amneal under the dispute resolution provision of the Metformin Agreement based on Amneal's alleged improper termination nor asked Amneal to rescind its termination of the Metformin Agreement.

## II. DISCUSSION

A preliminary injunction<sup>8</sup> is "an extraordinary remedy," one "to be granted only sparingly." In re Microsoft Litig., 333 F.3d 517, 524 (4th Cir. 2003). The purpose of a preliminary injunction is to protect the status quo and to prevent irreparable harm from occurring before the merits of a case are determined. Id. at 525. This circuit applies the hardship balancing test as set forth in Blackwelder Furniture Co. v. Seilig Mfg. Co., 550 F.2d 189 (4th Cir. 1977). Under Blackwelder, a court deciding whether to issue a preliminary injunction must weigh: (1) the likelihood of irreparable harm to the plaintiff if its request for relief is denied; (2) the likelihood of harm to the

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<sup>7</sup>AAA R-34, providing for interim measures, states that "[a] request for interim measures [including injunctive relief] addressed by a party to a judicial authority shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate."

<sup>8</sup>A temporary restraining order may be entered without notice to the burdened party and may not exceed ten days unless the court, for good cause, grants an extension of an additional ten days or the adverse party consents to a longer extension. Fed. R. Civ. P. 65(b). A preliminary injunction may be entered only after the burdened party is given notice. Fed. R. Civ. P. 65(a). Otherwise, the two forms of relief are indistinguishable and are governed by the same principles. See United States Dept. of Labor v. Wolf Run Mining Co., 452 F.3d 275, 281 n.1 (4th Cir. 2006).

defendant if the requested relief is granted; (3) the likelihood that the plaintiff will succeed on the merits of its claim; and (4) the public interest.<sup>9</sup> 550 F.2d at 195; accord Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 812 (4th Cir. 1991). The party seeking the preliminary injunction bears the burden of proving that each factor supports granting relief. Direx Israel, 952 F.2d at 812.

Under Fourth Circuit precedent, if a party clearly shows that a preliminary injunction is necessary to prevent irreparable injury, a court must then weigh that harm against the harm that the defendant will suffer if injunctive relief is granted. Id.; Scotts Co. v. United Indus. Corp., 315 F.3d 264, 271 (4th Cir. 2002). If “the balance tips decidedly in favor of the plaintiff,” then the Court must decide whether the plaintiff’s claims merit further investigation. Direx Israel, 952 F.2d at 812-13; see Scotts, 315 F.3d at 271 (explaining that if the balance of hardships favors the plaintiff, then generally it will be enough for the plaintiff to pose serious, substantial, difficult, and doubtful questions going to the merits). If, however, the balance of harms does not strongly favor the plaintiff, a stronger showing that the plaintiff is likely to succeed on the merits of its claims is necessary. Direx Israel, 952 F.2d at 813; Scotts, 315 F.3d at 271.

A plaintiff is required to show that it will sustain irreparable harm, that is neither remote nor speculative, but actual and imminent. Id. Irreparable injury is suffered when monetary damages are

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<sup>9</sup>The Supreme Court has not specified the order in which a court should analyze the factors, nor the weight it should give them. See Globe Nuclear Svcs. & Supply, Ltd. v. AO Techsnabexport, 376 F.3d 282, 287 (4th Cir. 2004). Although the Fourth Circuit has declared that the first two factors—the “balancing of harms” test—are the most important, see, e.g., Direx Israel, 952 F.2d at 812, more recently it has cautioned, albeit in dicta, that emphasizing those factors is contrary to Supreme Court precedent, see Scotts, 315 F.3d at 271 n. 2 (noting that “Blackwelder’s emphasis on the balancing of the harms rather than the likelihood of success has been criticized, even within this court, as inconsistent with Supreme Court precedent”).

difficult to ascertain or are inadequate. Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co., 22 F.3d 546, 551 (4th Cir. 1994). Additionally, “when the failure to grant preliminary relief creates the possibility of permanent loss of customers to a competitor or the loss of goodwill, the irreparable injury prong is satisfied.” Id. at 552. But, if the plaintiff’s loss is a matter of mathematic calculation, then the plaintiff fails to establish irreparable injury for preliminary injunction purposes. Id. at 551-52.

Further, an inordinate delay in initiating a preliminary injunction proceeding may “indicate an absence of the kind of irreparable harm required to support a preliminary injunction.” Quince Orchard Valley Citizens Ass’n, Inc. v. Hodel, 872 F.2d 75, 80 (4th Cir. 1989) (explaining that when “an application for [a] preliminary injunction is based upon an urgent need for the protection of [a] [p]laintiff’s rights, a long delay in seeking relief indicates that speedy action is not required”) (internal quotation marks omitted); accord Magnussen Furniture, Inc. v. Collezione Europa USA, Inc., 116 F.3d 472, 1997 WL 337465, at \*3 n.6 (4th Cir. 1997) (finding that the plaintiff’s purported need for immediate relief was belied by its failure to seek copyright protection for sixteen months and its delay in filing suit). But, the Fourth Circuit has cautioned that Quince Orchard does not hold, as a matter of law, that the plaintiff suffered no irreparable injury because it delayed in initiating its request for a preliminary injunction. Candle Factory, Inc. v. Trade Assoc. Group, Ltd., 23 F. App’x 134, 138 (4th Cir. 2001).

In this instance, Provident argues that as a result of Amneal rejecting Provident’s purchase orders and failing to provide the timely delivery of Benzonatate in accordance with Provident’s forecast and purchase orders, retail distributors, such as Walgreens and Associated Pharmacies, Inc., have terminated their product sales and purchase agreements with Provident. Provident maintains

that its inability to perform on its outstanding contracts with retail distributors will morph into a reputation for general unreliability as a merchant. Additionally, Amneal's refusal to continue to supply Provident with Metformin and Benzonatate will force Provident to change suppliers, and incur new regulatory costs and delays. As such, Provident asserts that it faces the threat of a permanent loss of customers and market share as well as the loss of goodwill and its reputation. Because Benzonatate and Metformin are the only two products that Provident markets, Amneal's actions could force Provident out of business entirely.

The Court finds that Provident has failed to demonstrate an imminent and actual threat of irreparable harm and, even if it had, the balance of harms does not tip decidedly in its favor. First, most of the harms alleged by Provident are past and accrued as any retailers that have terminated their contracts with Provident is a past, compensable loss. Similarly, any costs incurred by Provident due to a change in suppliers (i.e. regulatory costs and delays) are also ascertainable monetary damages. Thus, the crux of Provident's argument rests on its allegation that Amneal's alleged improper termination of the Metformin and Benzonatate Agreements will cause Provident a permanent loss of customers and market share, which could force Provident out of business.

With respect to the Metformin Agreement, Amneal issued its notice of termination in August 2007. Upon receipt of Amneal's notice of termination, Provident never attempted to utilize the dispute resolution provisions of the Metformin Agreement. Instead, Provident waited approximately eleven months, until the eve of the expiration of the twelve-month notice, to seek injunctive relief from this Court. Accordingly, Provident exacerbated its own condition. See Quince Orchard, 872 F.2d at 80; see also San Francisco Real Estate Investors v. Real Estate Inv. Trust of Am., 692 F.2d 814, 818 (1st Cir. 1982) (reasoning that the plaintiff's harm was largely self-inflicted and, therefore,



“it was not only not irreparable in the absence of the district court’s order, but entirely avoidable”); Southtech Orthopedics, Inc. v. Dingus, 428 F. Supp. 2d 410, 420-21 (E.D.N.C. 2006) (determining that the plaintiff’s delay indicated a lack of imminent and irreparable harm where the plaintiff waited at least six weeks after it knew of defendant’s hostile activities before seeking injunctive relief); Baer v. Nat’l Bd. of Med. Exam’r, 392 F. Supp. 2d 42, 49 (D. Mass. 2005) (plaintiff medical student failed to establish irreparable harm where she delayed filing suit until three weeks prior to medical exam despite receiving the defendant’s denial letter three months prior).

In contrast, Amneal, relying on its belief that it properly terminated the Metformin Agreement, made arrangements to use its manufacturing capacities for other projects and products. Further, Amneal states that its Metformin API supplier advised that there is a worldwide shortage of Metformin API, interfering with Metformin production throughout the world. Due to the current market conditions for Metformin API, Amneal represents that it is unable to manufacture and deliver Metformin product for Provident’s last two purchase orders.<sup>10</sup> Consequently, an injunctive order from this Court requiring Amneal to perform a commercially unfeasible, if not impossible, task would be of great harm to Amneal.

Similar obstacles exist with respect to the Benzonatate Agreement. It is undisputed that Benzonatate API is produced twice per year - first in March and second in October. Amneal states that to manufacture, package, and ship finished Benzonatate product requires four to six months of lead time. Although Provident argues that the Benzonatate Agreement requires Amneal to maintain an adequate supply of Benzonatate in stock, this does not alter the fact that Amneal can not produce

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<sup>10</sup>Amneal notes, however, that it will be able to fill two of the four outstanding purchases orders. (TRO Hr’g Tr. at 24-25.)

what it does not possess and cannot obtain since the Benzonatate API is only produced twice per year. Accordingly, it makes little sense for this Court to issue an injunction in July requiring Amneal to obtain a product that is produced only in March and October.

Finally, even assuming that the equities were balanced, Provident has failed to show a strong probability of success on the merits. This case involves a complex contractual dispute and, at this stage, a clear victor is not apparent. Relying on section 5.1 of the Metformin Agreement, Provident alleges that Amneal is obligated to manufacture Metformin for “a period of no less than 5 years following approval of the ANDA.” (Compl., Ex. 1.) Amneal rebuts that section 9.3 of the Metformin Agreement permits either party to terminate the agreement “for any reason by twelve (12) months prior written notice to the other party.” (Compl., Ex. 1.) At this juncture, both parties offer a reasonable interpretation of the Metformin Agreement. Additionally, Amneal raises serious defenses to Provident’s claims, particularly given the shortages of the Metformin API and Amneal’s assertion that Provident breached the agreement when it failed to provide the four to six months of lead time to manufacture, package, and ship finished Benzonatate. Thus, Provident has not demonstrated, as it must, the greater quantum of proof necessary where the balance of equities does not tip decidedly in its favor. See Direx Isreal, 952 F.2d at 813.

### III. CONCLUSION

For the foregoing reasons, the Court entered an Order DENYING Provident’s Motion for Temporary Protective Order and Preliminary Injunction.

Let the Clerk send a copy of this Memorandum Opinion to all counsel of record.

It is SO ORDERED.

/s/

**James R. Spencer**  
**Chief United States District Judge**

Entered this <sup>th</sup>15 day of August 2008